Frederick National Laboratory for Cancer Research



Implementation of the RAS Program

David C. Heimbrook, Ph.D. CEO, SAIC-Frederick

Presentation to Joint BSA / NCAB Meeting

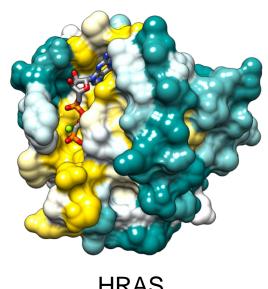
June 24, 2013

Frederick National Laboratory Missions What is RAS, and why is it so important?

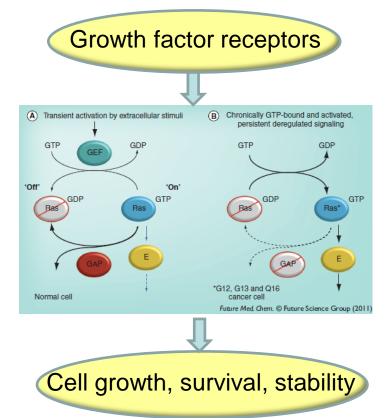


RAS stands for Rat Sarcoma viral oncogene homolog, and is a protein which is a key regulator of signal transduction in normal and cancerous cells

Four flavors: Harvey, Kirsten (A & B), and Neuroblastoma



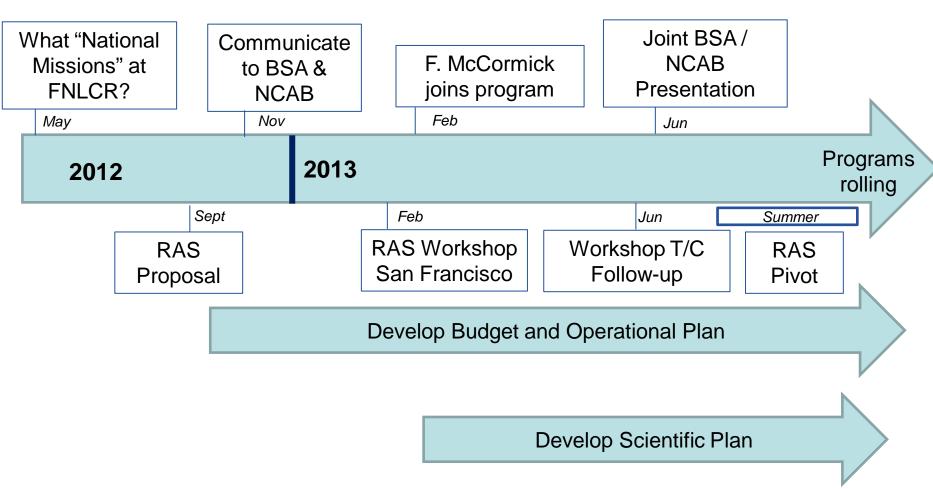
HRAS (Wikimedia commons)



Mutated RAS is found in ~33% of human cancers, is currently undruggable, and enables resistance to many existing cancer therapies



Etiology of the RAS Program at FNLCR



Full-Spectrum Research & Development at FNLCR



Research & Development

- Basic Research: New knowledge about AIDS and cancer
- Applied R&D: New diagnostics and therapeutics
- Clinical Research: Clinical trials and laboratory analysis
- cGMP manufacturing: Biologicals and vaccine production



Specialties

- Genomics, proteomics, and metabolomics
- Bioinformatics and imaging
- Nanotechnology
- Animal models
- Tumor cell biology and virology
- Immunology and inflammation



Customers

NCI, NIH, and external academic and commercial biomedical scientists

4

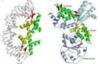
Implementing "National Missions" at FNLCR The RAS Hub



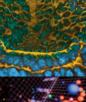
Essential capabilities....



Genetics and Genomics



Proteins and Proteomics



Imaging and Nanotechnology



Advanced Biomedical Computing



Cell Biology

...integrated into a brand new state-of-the-art Research Facility



Advanced Technology Research Facility Opened June 2012



Integrated *in vivo* support at Frederick & Bethesda

Operationalizing the RAS Program Hub and Spoke model

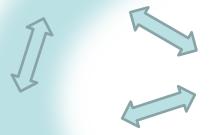


Intramural Labs





FNLCR – The Hub







Biotechs







Pharma

Extramural NCI-Supported Labs







Contract Research

Hub Partnerships Facilitated through NCI and Contractor Mechanisms



Material Transfer Agreement (MTA)

- Research materials transferred (in or out); research plan
- No fees; No joint IP

Technical Services Agreement

- Purchase of contractor-developed assays or reagents
- Minimal paperwork; Assay list online
- Cost recovery only

Collaboration Agreement

- Research materials transferred (in or out);
- Research plan developed
- Both contribute intellectually; no \$\$ to NCI

Cooperative Research & Development Agreement (CRADA)

- R&D collaboration both partners contribute intellectually
- Both contribute resources; can include \$\$ to NCI
- Both NCI and Contractor mechanisms

http://frederick.cancer.gov/

The RAS Program Funding Model



Funding for FNLCR RAS Hub

- Approximately \$10 M / yr from NCI-directed re-prioritization of ongoing activities within the existing FFRDC contract - <u>No new money</u>
 - The Advanced Technology Program "Pivot" re-orients a predominantly intramural effort towards driving the RAS Hub
 - Additional "one-time" funds from within the existing contract facilitate start-up activities
- This funding supports ongoing research activities within the Hub, as well as initial phase of subcontracts between the Hub and external laboratories

Funding for RAS Spokes

- Contract Research Organization subcontracts from FNLCR RAS Hub
- Pharma, Biotech Self-funded
- Academic: Some subcontracts from FNLCR RAS Hub;
 - Existing and future grantees working on RAS will have the opportunity to participate in RAS program

The RAS Program Oversight and Governance



Oversight

- An NCI-Frederick Advisory Committee (NFAC) subgroup will be formed
 - Will include NFAC members and representatives from academia and industry (TBD)

Research Program Prioritization

 Joint recommendations by RAS Program leadership (Frank McCormick and SAIC-F leadership) and RAS Program oversight group, with concurrence by NCI Leadership (Drs. Varmus and Lowy)